440. Misbranding of Cascarin Compound Tablets. U. S. v. 573 Bottles of S. C. Tablets Cascarin Compound Dr. Hinkle No. 3. Default decree of condemnation and destruction. (F. D. C. No. 3638. Sample No. 32634–E.)

On January 9, 1941, the United States attorney for the District of Arizona filed a libel against 573 bottles of the above-named product at Phoenix, Ariz., alleging that the article had been shipped by the Boyce Pharmacal Co. from Los Angeles, Calif., on or about July 10, 1940; and charging that it was misbranded.

Analysis of a sample showed that the tablets each contained alkaloidal material including strychnine sulfate (approximately 0.024 grain), podophyllin (approximately ⅛ grain), aloin (¼ grain), and an emodin-bearing drug such as cascara sagrada.

The article was alleged to be misbranded in that the label failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it did not inform the purchaser that the tablets should not be taken when symptoms of appendicitis are present and that its use by children and elderly persons is particularly dangerous, and did not warn against frequent or continued use of the article when such use is capable of causing dependence upon laxatives to move the bowels. It was alleged to be misbranded further (1) in that the designation "Cascarin Compound," appearing on the label, was false and misleading since it suggested that the essential ingredient in the preparation was derived from some species of cascara when in fact its principal active ingredients were aloin, podophyllin, and strychnine; (2) in that the designation "Dr. Hinkle No. 3," appearing on the label, was false and misleading since it created the impression that the article had the essential composition described in the National Formulary for Hinkle's pills when in fact its composition differed therefrom, particularly in that it contained strychnine sulfate, which is not an ingredient of Hinkle's pills; and (3) in that the label failed to bear the common or usual name of each of its active ingredients since the coined word "Cascarin," appearing on the label in the list of ingredients, was not the common or usual name of any drug.

On February 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

441. Misbranding of Crawford's Sa-Lax and Crawford's Formula 53 with Vitamin E. U. S. v. 9 Bottles and 4 Bottles of Crawford's Formula 53 with Vitamin E and 50 Tins of Crawford's Sa-Lax. Default decree of condemnation and destruction. (F. D. C. Nos. 3556, 3558. Sample Nos. 32615–E, 32622–E.)

The label of Crawford's Sa-Lax failed to bear adequate directions and warning statements; and the labeling of both products bore false and misleading therapeutic claims.

On January 6, 1941, the United States attorney for the District of Arizona filed a libel against the above-named products at Tucson, Ariz., alleging that Crawford's Formula 53 had been transported on or about July 18, 1940, by Walter Bopp from Eagle Rock, Calif., and that Crawford's Sa-Lax had been transported on or about July 26, 1940, by Crawford Foods, Inc., from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the articles showed that Crawford's Sa-Lax Tablets contained the laxative drugs rhubarb root and senna leaf together with Irish moss, okra, and leafy plant materials such as parsley; and that Crawford's Formula 53 Tablets contained plant materials, largely alfalfa (lucerne) leaf and stem tissues, with smaller proportions of other plant materials including tomato seed, anise, fennel, Cayenne pepper (capsicum), celery seed, a leafy material such as parsley, and yeast.

Crawford's Sa-Lax was alleged to be misbranded (1) in that its package failed to bear adequate directions for use since the directions on the bottle label, "The dosage of Crawford's Sa-Lax must be determined by the severity of the case. The adult dosage suggested is two tablets upon retiring, to be increased to one tablet four times per day, with meals and upon retiring in the more severe cases. Children in proportion to age," were not suitable nor appropriate directions for the use of a laxative preparation of the composition of this one and therefore were not adequate; and (2) in that its labeling failed to bear adequate warnings against use in certain pathological conditions or methods or duration of administration in such manner and form as are necessary for the protection of users since its label failed to inform the purchaser that it would be dangerous if

consumed by a person suffering from appendicitis, and it failed to inform purchasers that frequent or continued use might result in dependence on laxatives. It was alleged to be misbranded further in that the following statements appearing on the bottle label were false and misleading with respect to the active laxative ingredients and with respect to the effects it would produce upon the consumer: "The active principles in this formula are parsley and asparagus. Parsley and asparagus appear to maintain a higher alkalinity through the intestine and into the colon than do other vegetables of higher initial alkaline content. Any decrease in the acidity of the waters absorbed from the colon and carried by the portal circulation to the liver evidently minimizes the alkaline demand upon the liver to bind such acid. Any conservation of the alkaline demand upon the liver facilitates the liver's fabrication and secretion of a more alkaline or normal bile, which will result in more complete digestion, minimized fermentation and lowered putrefaction within the colon. Neither parsley nor asparagus produces any laxative effect. Okra is included in this formula for the excellent property of its vegetable mucin. Irish moss is included for its property of absorbing and holding the water and thus effecting a higher degree of softness of the colonic residues."

Crawford's Formula 53 with Vitamin E was alleged to be misbranded in that representations and suggestions in the labeling that it would be efficacious in building blood, supplying the necessary vitamins and minerals to the blood stream for restoring the normal functions of the body mechanism; that it would be efficacious in maintaining the tone of the sacral nervous system, in helping to maintain the sex power, in helping to maintain high vitality through building up the entire glandular system; that it would aid in building up the skin tissuses and that it would endow the blood with such properties as would give the consumer long life, health, energy, and vitality; that it would be efficacious in case of pale and livid complexion, dry skin, bluish, white, or gray gums, transparent and waxy ears, habitually cold feet, continually clammy hands, bluish and lusterless fingernails, dull-looking hair, decaying teeth, pyorrhea, drawn face, coarse and yellow skin, or foul breath; that it would be efficacious when physical exertion causes shortness of breath, palpitation of the heart, or rapid or weak pulse; that it would be efficacious when mental and emotional fatigue are present, when one feels fear or apprehension, loses faith in oneself, or is nervous, listless, unstable, and despondent; that because of its ability to form red cells in the blood and increase the amount of hemoglobin in the red cells it would be efficacious in anemia accompanied by lack of energy, languor, fatigue, and lack of persistence; that it would be efficacious in nourishing and rebuilding the tissues, regardless of the nature of the ailment; that it would be efficacious in the treatment of arthritis, rheumatism, heart disease, degenerative diseases, and bladder, liver, and kidney troubles; and that it would develop a strong friendly overpowering personality which would command the respect and love of everyone and allow the user to be more useful to himself, friends, and children; that it would be efficacious when one is grouchy, tired, feeling miserable, cannot sleep, and is suffering from pains all over the body; that it would rejuvenate the body; that it would be efficacious for the treatment of tumors and growths such as cancer by dissolving the tumor and growth; and that its use would enable the user to regain health and vigor, were false and misleading since it would not be efficacious for such purposes.

The libel alleged that Crawford's Formula 53 was also misbranded under the food provisions of the law as reported in F. N. J. No. 2819.

On February 21, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

442. Misbranding of Germania Herb Tea. U. S. v. 1,250 Packages of No. 14 Germania Herb Tea. Default decree of condemnation and destruction. (F. D. C. Nos. 3816, 3817. Sample Nos. 40253-E, 40254-E.)

The label of this product not only failed to bear adequate directions for use; but it contained false and misleading statements regarding its efficacy as an aid in weight reduction and in the treatment of various diseases, and it failed to bear the common or usual name of each of the active ingredients.

On February 14, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 600 sample packages and 650 retail packages of Germania Herb Tea at Philadelphia, Pa., alleging that it had been shipped by the Germania Tea Co. from Minneapolis, Minn., and by Consolidated Drug Trade